REMARKS

The above-referenced Office Action has been carefully reviewed and reconsideration thereof is respectfully requested.

Claims 1-4 have been rejected as being based on a defective reissue oath under 35 USC 251. Applicant respectfully traverses this ground of rejection.

The reissue declaration by the inventor filed with the application contains the language assertedly missing. A copy thereof is enclosed herewith.

Claims 1-4 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of US Patent No. 5,912,478. Applicant respectfully traverses this ground of rejection.

The Examiner states that "the instant claims are drawn to methods for treating malignant tumors, while the patent claims are directed to methods for inhibiting tumor necrosis factor (which would include neoplastic disease, col. 20, line 4) by administering the claimed substance". It is respectfully submitted that that reference in the patent in no way refers to the treatment of malignant tumors or any other types of tumors. It only states that in various types of diseases, which include usually some injury to tissue or cells, major untoward amounts of TNF-alpha are discharged from the adjacent tissue or cells and that pirfenidone is capable of blocking this discharge of TNF-alpha from these cells or tissues. There is no implication that pirfenidone as a TNF-alpha inhibitor can be used to treat a malignant tumor or a benign tumor. As a matter of fact, the neoplastic reference in col. 20, line 4 is among several types of situations where the injured tissue causes a release of TNF-alpha which then, in turn, can be prevented by the administration of pirfenidone.

At the top of column 20, it is stated, "These actions relate to their novel use as pyridones in treating tissue trauma, or other injury disorders caused by infection, allergy, immunological phenomena, burns, radiation exposure, and [then there is a mention of neoplastic disease] and following thereafter by toxic chemicals, cardiovascular damage, neurologic injury, renal damage, liver damage, pancreatic damage; as well as ascites,

localized edema dermal damage and derma blisters." Thus, the word "neoplastic disease" is only one of a number of circumstances which can cause the discharge of major harmful amounts of TNF-alpha in the tissues surrounding the existing injury site. It has absolutely nothing to do with treating any type of tumor and there is absolutely no representation of a treatment for any type of tumors by pirfenidone anywhere in the patent.

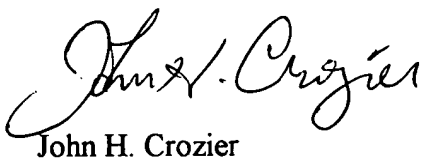
Claims 1-4 have been rejected under 35 USC 112, first paragraph, and the Examiner has suggested language that would overcome this rejection. The suggested language is read as "changing the term 'tumor malignant' to 'malignant tumor sensition to the compound". Unfortunately, the new language is not understood. The Examiner is respectfully requested to clarify the same.

Claims 1-4 have been rejected under 35 USC 112, second paragraph as being indefinite.

It is believed that the above amendments to Claims 1 and 4 fully overcome this ground of rejection.

Date: December 21, 2001.

Respectfully submitted,



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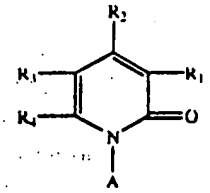
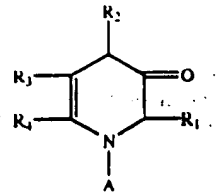
CLEAN SET OF CLAIMS AFTER AMENDMENT

1. A method of treating benign or malignant lymphoma, leukemia, and/or leiomyoma tumors in a laboratory animal or a human, comprising: administering to said laboratory animal or said human an effective dose of a composition including one or more pharmaceutical substances selected from the group consisting of N-substituted 2-(1H) pyridones, N-substituted 3-(1H) pyridones, and pharmaceutically acceptable salts thereof, wherein said 2-(1H) pyridones have the following general structural formula



where: R1 is selected from the group consisting of (1) an alkyl group, with R3 hydrogen, and (2) hydrogen, with R3 consisting of an alkyl group; A is an aryl group; and R2 and R4 are hydrogen; and wherein said 3-(1H) pyridones have the following general structural formula



where: R2 is selected from the group consisting of (1) an alkyl group, with R3 hydrogen, and (2) hydrogen, with R3 consisting of an alkyl group; A is an aryl group; and R1 and R4 are hydrogen.

2. A method, as defined in Claim 1, wherein: said composition is administered orally or parenterally to said laboratory animal at a rate of from about 20 to about 60 mg/kg of body weight per day.

3. A method, as defined in Claim 1, wherein: said composition is administered orally or parenterally to said human at a rate of from about 20 to about 60 mg/kg of body weight per day.

4. A method of treating benign or malignant lymphoma, leukemia, and/or leiomyoma tumors in a laboratory animal or a human, comprising: administering to said laboratory animal or said human an effective dose of a composition including one or more pharmaceutical substances selected from the group consisting of N-substitued 2-(1H) pyridones, N-substituted 3-(1H) pyridones, and pharmaceutically acceptable salts thereof, said N-substituted 2-(1H) pyridones and said N-substituted 3-(1H) pyridones being selected from the group consisting of: 5-Methyl-1-phenyl-2-(1H) pyridone, 5-Methyl-1-(3-nitrophenyl-2)-(1H) pyridone,5-Methyl-1-(4'-methoxyphenyl)-2-(1H) pyridone, 5-Methyl-1-p-tolyl-2-(1H) pyridone, 5-Methyl-1-(3'-trifluoromethylphenyl)-2-(1H) pyridone,1-(4'Chlorophenyl)-5-methyl-2-(1H)

pyridone, 5-Methyl-1-(2'-naphthyl)-2-(1H) pyridone, 5-Methyl-1-(1'-naphthyl)-2-(1H) pyridone, 3-Methyl-1-phenyl-2-(1H) pyridone, 6-Methyl-1-phenyl-2-(1H) pyridone, 3,6-Dimethyl-1-phenyl-2-(1H) pyridone, 5-Methyl-1-(2'thienyl)-2-(1H) pyridone, 1-(2'-Furyl)-5-methyl-2-(1H) pyridone, 5-Methyl-1-(5'-quinolyl)-2-(1H) pyridone, 5-Methyl-1-(4'-pyridyl)-2-(1H) pyridone, 5-Methyl-1-(3'-pyridyl)-2-(1H) pyridone, 5-Methyl-1-(2'-pyridyl)-2-(1H) pyridone, 5-Methyl-1-(2'-quinolyl)-2-(1H) pyridone, 5-Methyl-1-(4'-quinolyl)-2-(1H) pyridone, 5-Methyl-1-(2'-thiazolyl)-2-(1H) pyridone, 1-(2'-Imidazolyl)-5-methyl-2-(1H) pyridone, 5-Ethyl-1-phenyl-2-(1H) pyridone, 3-Ethyl-1-phenyl-2-(1H) pyridone, 1-Phenyl-2-(1H) pyridone1-(4'-Nitrophenyl)-2-(1H) pyridone, 5-Methyl-3-phenyl-1-(2'-thienyl)-2-(1H) pyridone, 5-Methyl-1-phenyl-3-(1H) pyridone, 5-Methyl-1-(4'-methoxyphenyl)-3-(1H) pyridone, 5-Methyl-1-p-tolyl-3-(1H) pyridone, 1-(4'-Chlorophenyl)-5-methyl-3-(1H) pyridone, 5-Methyl-1-(2'-naphthyl)-3-(1H) pyridone, 4-Methyl-1-phenyl-3-(1H) pyridone, 6-Methyl-1-pheyl-3-(1H) pyridone, 5-Methyl-1-(2'-thienyl)-3-(1H) pyridone, 1-(2'-Furyl)-5-methyl-3-(1H) pyridone, 5-Methyl-1-(5'-quinolyl)-3-(1H) pyridone, 5-Methyl-1-(3'-pyridyl)-3-(1H) pyridone, 5-Methyl-1-(2'-pyridyl)-3-(1H) pyridone, 5-Methyl-1-(2'-quinolyl)-3-(1H) pyridone, 5-Ethyl-1-phenyl-3-(1H) pyridone, and 1-Phenyl-3-(1H) pyridone.